



HENRY FORD HOSPITAL

1441 '99 OCT 22 P134

2799 West Grand Boulevard
Detroit, Michigan 48202

October 14, 1999

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Comments on docket #98N-0607

To Whom It May Concern:

The requirement to notify deferred donors of the possibility of re-entry as part of the deferral notification would make the deferral notice longer and potentially more confusing. Very few donors, once permanently deferred, ever return for re-entry, even when it is offered. Providing a telephone number of the donor facility for questions concerning the notification would allow the donor to be informed of the possibility of re-entry, if it applied. As re-entry protocols change as new testing is identified, the additional burden of changing notification materials every time a re-entry protocol changes would be avoided.

Notification of autologous donors of repeatedly reactive and supplemental test results should not be required under the proposed rule. As reactive autologous units do not enter the general blood supply, codification of a step that does not provide additional safety is not warranted. Very few autologous donors return to voluntarily donate blood. It is already standard practice in the industry to notify patients and physicians of repeat reactive testing. The patient's physician should make the decision as to whether to pursue supplemental testing, as it applies to each individual case.

The proposed rule should not require notification of donors who are repeatedly reactive for HTLV, types I and II, or anti-HBc on only one occasion, but should provide for donor notification on the second repeatedly reactive donation. Given the high rate of false reactive results found on both of these tests in the healthy population, such notification would cause unnecessary worry, and perhaps pointless testing, for these individuals, without positively impacting the safety of the blood supply.

The rule should be written in such a fashion that establishments have the flexibility to convey the information in 21 CFR 630.6(b) in a manner suitable for the individual donor. Conveying this information in letter form to a donor who is confirmed positive for HIV, for example, may have potentially disastrous consequences. In addition, even registered, restricted delivery may allow such a letter to fall into the wrong hands, compromising confidentiality.

I appreciate the opportunity to comment on the proposed rule.

Sincerely,

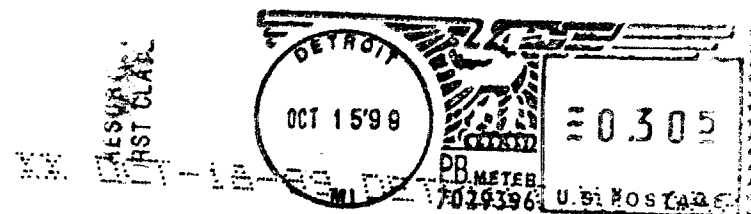
Mary Jo Drew, MD
Division Head, Transfusion Medicine
Medical Director, Blood Bank

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Blood Bank
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AUTO 20857

